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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,000	11/14/2003	Vanessa Chisholm	P1746R1P1	1570
9157	7590	09/26/2006	EXAMINER	
GENENTECH, INC.			GUIDRY, GUY L	
1 DNA WAY			ART UNIT	
SOUTH SAN FRANCISCO, CA 94080			PAPER NUMBER	

1636

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/714,000	Applicant(s) CHISHOLM ET AL.	
	Examiner Guy Guidry, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-61 and 63-102, 104-116 is/are pending in the application.
- 4a) Of the above claim(s) 91,92,100,101,112 and 114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-61,63-90,93-99,102,104-113,115 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/2006, 7/5/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response filed 30 June 2006 to the Office Action mailed 9 September 2005 and to the Notice of Non-Compliant amendment mailed 31 May 2006. Claims 1-58, 62 and 103 are canceled. Claims 91-92, 100-1010, 112 and 114 are withdrawn. Claims 59, 63, 66, 71, 72, 76, 79, 88, 97, 106, 108, 109 and 115 have been amended. Claims 59-61 and 63-116 are currently pending in this application. Claims 59-61, 63-90, 93-99, 102, 104-113, 115 and 116 are under consideration in this Action. All previous objections/rejections not repeated herein are hereby withdrawn. Previous rejections to canceled claims have been rendered moot by Applicant's cancellation of those claims. A response to Applicant's arguments will be set forth, where appropriate, immediately following any statement of rejection repeated herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61, 63-90, 93-99, 102, 104-113, 115 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This is a new ground of rejection. The limitation "amplifiable" is poorly defined, rendering the claims indefinite. The claims are directed to a fusion gene comprising a first selectable gene and an amplifiable second selectable gene. The claim limitation

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"amplifiable" is defined in the specification as "additional copies of the gene are generated which survive in intrachromosomal or extrachromosomal form" (p. 13, ¶2). As the first selectable and second amplifiable genes are fused on one polynucleotide, it is not clear how the second selectable gene could be amplified without amplification of the first selectable gene. This ambiguity renders the claims indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61, 63-90, 93-99, 102, 104-113, 115 and 116 rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new ground of rejection. The amendments to claims 59, 72 and all dependent claims wherein "the first selectable marker gene is not amplifiable" represents the introduction of inadmissible NEW MATTER. The disclosure contains no teaching with respect to a first selectable gene that is not amplifiable. Indeed, based on the definition of "amplifiable" provided in the specification wherein "additional copies of the gene are generated which survive in intrachromosomal or extrachromosomal form" (p. 13, ¶2), any gene may be considered "amplifiable" even if simply duplicated once.

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The disclosure is silent as to the particulars of how a selectable gene may not be duplicated or amplified. Further, as the first selectable gene and the second selectable gene are fused on one polynucleotide, then if the second gene is amplified then the first selectable gene would necessarily be amplified as well; it is not clear how the first selectable gene could not be duplicated or copied and therefore amplified.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

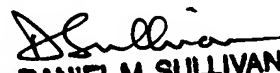
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Guy Guidry, Ph.D.

Examiner

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DANIEL M. SULLIVAN
PATENT EXAMINER